IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

INSYS THERAPEUTICS, INC. and INSYS DEVELOPMENT COMPANY, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
ALKEM LABORATORIES LTD. and S&B PHARMA, INC.	)	
Defendants.	)	

COMPLAINT

Plaintiffs Insys Therapeutics, Inc. ("Insys Tx") and Insys Development Company, Inc. ("Insys Dev") (collectively, "Insys" or "Plaintiffs"), for their Complaint against Defendants Alkem Laboratories Ltd. ("Alkem") and, S&B Pharma, Inc. ("S&B") (collectively, "Defendants"), hereby allege as follows:

The Parties

1. Insys Tx is a corporation organized and existing under the laws of Delaware, having a principal place of business at 1333 South Spectrum Boulevard, Suite 100, Chandler, Arizona 85286.

2. Insys Dev is a corporation organized and existing under the laws of Delaware, having a principal place of business at 1333 South Spectrum Boulevard, Suite 100, Chandler, Arizona 85286. Insys Dev is a wholly owned subsidiary of Insys Tx.

3. Upon information and belief, Alkem is a corporation organized and existing under the laws of India, having a principal place of business at Devashish Building, Alkem House, Senapati Bapat Road, Lower Parel, Mumbai: 400 013, India.

4. Upon information and belief, S&B is a corporation organized and existing under the laws of Delaware, having a principal place of business at 405 S. Motor Ave., Azusa, CA 91702. Upon information and belief, S&B is a wholly owned subsidiary of Alkem.

Nature of the Action

5. This is a civil action for infringement of United States Patent Nos. 8,222,292 ("the '292 patent") and 9,345,771 ("the '771 patent"); (collectively, "the patents-in-suit"). This action arises under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq*.

Jurisdiction & Venue

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

8. Upon information and belief, S&B's registered agent to accept service of process is The Corporation Trust Company, Corporation Trust Center 1209 Orange Street, Wilmington, Delaware 19801.

9. This Court has personal jurisdiction over Defendants, and venue is proper in this district, by virtue of the facts that, *inter alia*, S&B is a Delaware corporation and thus resides in Delaware, and Defendants have committed, aided, abetted, contributed to, and/or participated in the commission of a tortious act of patent infringement under 35 U.S.C. § 271(e)(2) that has led and/or will lead to foreseeable harm and injury to Plaintiffs, including in the State of Delaware. Alkem has indicated that it intends to engage in the commercial manufacture, use, or sale of Dronabinol Oral Solution, 5 mg/mL ("the ANDA Product") under Abbreviated New Drug Application No. 210825 ("the '825 ANDA") before the expiration of the patents-in-suit, throughout the United States, including in the State of Delaware.

10. Upon information and belief, Alkem is in the business of, *inter alia*, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, including in the State of Delaware, through its own actions, and through the actions of its agents and affiliates, including, at least, S&B.

11. Upon information and belief, S&B is in the business of, *inter alia*, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, including in the State of Delaware, through its own actions, and through the actions of its agents and affiliates.

12. Upon information and belief, Defendants have participated and collaborated in the preparation, filing, and seeking FDA approval of the '825 ANDA for the ANDA Product; continue to participate and collaborate in seeking FDA approval of the '825 ANDA; and intend to participate and collaborate in the commercial manufacture, marketing, offer for sale, and sale of the ANDA Product throughout the United States including the State of Delaware.

13. Defendants' infringing activities with respect to the filing of the '825 ANDA and intent to commercialize the ANDA Product have led and/or will lead to foreseeable harm and injury to Plaintiffs.

14. This Court also has personal jurisdiction over Defendants, and venue is proper in this district, by virtue of the fact that, upon information and belief, *inter alia*, Defendants have availed themselves of the rights and benefits of Delaware law, and have engaged in systematic and continuous contacts with the State of Delaware.

15. This Court also has personal jurisdiction over Alkem, and venue is proper in this district, because it has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in

this jurisdiction. *See, e.g.*, *Shire Dev. LLC v. Alkem Labs. Ltd.*, C.A. No. 16-747-LPS-CJB; *Acorda Therapeutics, Inc. v. Alkem Labs. Ltd.*, C.A. No. 14-917-LPS; *Pfizer Inc. v. Alkem Labs. Ltd.*, C.A. No. 13-1110-GMS; *Medicis Pharm. Corp. v. Alkem Labs. Ltd.*, C.A. No. 12-1663-LPS; *Amgen Inc. v. Alkem Labs. Ltd.*, C.A. No. 17-815-GMS; *Sanofi v. Alkem Labs. Ltd.*, C.A. No. 15-1200-RGA.

Insys's NDA and the Patents-In-Suit

16. Insys holds New Drug Application ("NDA") No. 205525 on SYNDROS™ (dronabinol oral solution), 5 mg/mL, and is the exclusive distributor of SYNDROS™ in the United States.

17. On July 17, 2012, the '292 patent, entitled "Liquid Cannabinoid Formulations" was duly and legally issued to Insys Tx. A copy of the '292 patent is attached as Exhibit A.

18. Insys Dev owns the '292 patent.

19. On May 24, 2016, the '771 patent, entitled "Oral Cannabinoid Formulations" was duly and legally issued to Insys Dev. A copy of the '771 patent is attached as Exhibit B.

20. Insys Dev owns the '771 patent.

21. The patents-in-suit are listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") for SYNDROS™.

Alkem's ANDA and Paragraph IV Notification

22. Upon information and belief, Alkem, with the collaboration or assistance of S&B, submitted the '825 ANDA to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), including a certification with respect to the patents-in-suit under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, seeking approval to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or

importation into the United States, of the ANDA Product prior to the expiration of the patents-in-suit.

23. Plaintiffs received written notification of Alkem's ANDA and its accompanying § 505(j)(2)(A)(vii)(IV) certification by a letter ("Paragraph IV Notification"), dated August 31, 2017, and sent via Federal Express and certified mail.

24. This action is being commenced by Plaintiffs within 45 days of the date of their receipt of the Paragraph IV Notification.

25. The Paragraph IV Notification was accompanied by an Offer of Confidential Access ("OCA") to certain confidential information regarding the ANDA Product. Insys subsequently negotiated with Alkem in an effort to agree on reasonable terms for such confidential access. As of the time of filing of this Complaint, however, the parties have not able to reach an agreement with respect to a revised OCA that addresses reasonable revisions proposed by the Plaintiffs.

26. To date, Defendants have not provided Plaintiffs with a copy of any portions of the '825 ANDA or any information regarding the ANDA Product, beyond the information set forth in the Paragraph IV Notification.

27. The limited information relating to the ANDA Product that was provided in the Paragraph IV Notification does not demonstrate that the ANDA Product, which Alkem is asking the FDA to approve for sale in the U.S., will not fall within the scope of issued claims of the patents-in-suit.

Alkem's Infringement of the Patents-In-Suit

28. Plaintiffs re-allege paragraphs 1–27 as if fully set forth herein.

29. By seeking approval of the ’825 ANDA to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of the ANDA Product prior to the expiration of the patents-in-suit, Defendants have infringed those patents under 35 U.S.C. § 271(e)(2)(A).

30. Defendants are jointly and severally liable for infringement of the patents-in-suit under 35 U.S.C. § 271(e)(2)(A). Upon information and belief, Defendants actively and knowingly caused to be submitted, assisted with, participated in, contributed to, or directed the submission of the ’825 ANDA seeking to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of the ANDA Product prior to the expiration of the patents-in-suit.

31. Moreover, if Defendants manufacture, use, offer for sale, or import into the United States any of the ANDA Product, or induce or contribute to any such conduct, prior to the expiration of the patents-in-suit, including any applicable exclusivities or extensions, they would infringe one or more claims of those patents-in-suit under 35 U.S.C. § 271(a), (b) and/or (c).

32. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of the ’825 ANDA be a date that is not earlier than the expiration date of the patents-in-suit, or any later expiration of any patent term extension or exclusivity for the patents-in-suit to which Plaintiffs become entitled.

33. Plaintiffs will be irreparably harmed by Defendants’ infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Prayer for Relief

Plaintiffs request that the Court grant the following relief:

A. An order adjudging and decreeing that Defendants have infringed the patents-in-suit by submitting the ’825 ANDA to the FDA;

B. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the ’825 ANDA will not be earlier than the expiration date of the patents-in-suit, or any later expiration of any patent term extension or exclusivity for the aforementioned patents-in-suit to which Plaintiffs are or become entitled;

C. An order permanently enjoining Defendants, their directors, officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in privity or concert with them, from manufacturing, using, offering to sell, selling, marketing, distributing, or importing the ANDA Product identified in this Complaint, or any product that infringes the patents-in-suit, prior to the expiration of the patents-in-suit, including any extensions to which Plaintiffs are or become entitled;

D. That Plaintiffs be awarded monetary relief to the extent Defendants commercially manufacture, use, offer for sale, or sell within the United States, or import into the United States any product that infringes or induces or contributes to the infringement of the patents-in-suit, within the United States prior to the expiration of the aforementioned patents, including any later expiration of any patent term extension or exclusivity for the patents to which Plaintiffs are or will become entitled, and that any such monetary relief be awarded to Plaintiffs with prejudgment interest; and

E. Such other and further relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Maryellen Noreika

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